



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19R5.D0
True Name	Brachyspira Hyodysenteriae Vaccine, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health
Date of Compilation Summary	May 17, 2018

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Safety												
<b>Pertaining to</b>	All												
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions												
<b>Product Administration</b>	Two doses were administered intramuscularly, 3 weeks apart												
<b>Study Animals</b>	314 pigs, 21-26 days of age, distributed among 3 study sites												
<b>Challenge Description</b>	NA												
<b>Interval observed after challenge</b>	Animals were monitored on days 2, 7 or 8, 21, 23, 28, and 42.												
<b>Results</b>	<table border="1"> <thead> <tr> <th>Frequency of adverse events out of 628 possible (313* pigs)</th> <th>Number</th> </tr> </thead> <tbody> <tr> <td>Injection Site Swelling**</td> <td>13</td> </tr> <tr> <td>Lethargy***</td> <td>396</td> </tr> <tr> <td>Death****</td> <td>7</td> </tr> <tr> <td>Diarrhea</td> <td>1</td> </tr> <tr> <td>No adverse events</td> <td>211</td> </tr> </tbody> </table> <p>*One pig was removed from the study due to a dropped tag.  **Injection site reactions (swelling) were observed in 9 pigs 21 days after the first vaccination; 8 of these had resolved by day 42. Injection site reactions were observed in 4 pigs 21 days after the second vaccination (study day 42).  ***Lethargy reported at two sites immediately following primary and booster vaccinations and resolved the next day.  ****Deaths affirmed by study cooperator as not attributable to vaccine.</p>	Frequency of adverse events out of 628 possible (313* pigs)	Number	Injection Site Swelling**	13	Lethargy***	396	Death****	7	Diarrhea	1	No adverse events	211
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<b>USDA Approval Date</b>	December 28, 2017												